

Exhibit C



Deposition of:
Michael Streiff , M.D.

July 12, 2017

In the Matter of:
**In Re: Bard IVC Filters Products
Liability**

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1 Q. And the reason why evidence-based
2 medicine is important is because you don't want
3 doctors relying on unreliable and incomplete
4 information, fair?

5 A. True. You want the best information
6 possible.

7 Q. Because if you have incomplete
8 information or unreliable information, that may
9 actually hurt patients in a situation?

10 A. Possibly if you don't have -- yeah.

11 Q. All right. So turning to your kind of
12 area of expertise. Your expertise is in hematology
13 and oncol-, oncology?

14 A. Primarily -- I mean, I did a
15 hematology-oncology fellowship, but I would say
16 that my primary focus is in benign hematology, and
17 primarily in clotting and bleeding disorders.
18 Although, I see other benign hematology diseases,
19 anemia, low blood, you know, low platelet counts,
20 sickle cell disease, but I think most of my work is
21 in blood clots or bleeding disorders.

22 Q. Okay. So you are not a doctor that
23 places or removes IVC filters?

24 A. True.

25 Q. And have you ever placed or removed an

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1 IVC filter?

2 A. No.

3 Q. Okay. And you're not a member of the
4 Society of Interventional Radiology, correct?

5 A. No.

6 Q. And you're not a member of the American
7 College of Radiology?

8 A. No.

9 Q. Okay. I just -- just I want to clear a
10 few areas of expertise to make sure we're on the
11 same page.

12 A. Sure.

13 Q. You have no training or experience or
14 education in engineering?

15 A. No.

16 Q. So you don't hold yourself out as an
17 engineering expert?

18 A. No.

19 Q. And you're not offering any opinions in
20 this case about the design or engineering of IVC
21 filters?

22 A. No.

23 Q. Okay. And you have never done any bench
24 testing relating to IVC filters?

25 A. No.

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1 Q. And you don't have any training or
2 education designing bench tests for IVC filters?

3 A. No.

4 Q. So I assume you have no experience
5 manufacturing IVC filters, medical devices?

6 A. No.

7 Q. Okay. And the same as far as marketing
8 IVC filters, it's fair to say you don't have any
9 expertise as far as the marketing of IVC filters?

10 A. No.

11 Q. And you wouldn't say you're an expert in
12 the manufacture or marketing of IVC filters?

13 A. No.

14 Q. As far as corporate ethics, you wouldn't
15 consider yourself an expert in corporate, corporate
16 ethics?

17 MR. O'CONNOR: Form.

18 THE WITNESS: No. Huh-uh.

19 BY MR. LERNER:

20 Q. You have no education, specific training
21 about corporate, corporate ethics?

22 A. No. No.

23 Q. Okay. And then you're not an expert in
24 reviewing and summarizing internal corporate
25 documents?

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1 A. No.

2 Q. And no training or experience in doing
3 that?

4 MR. O'CONNOR: Excuse me. Belated
5 objection. Form and foundation.

6 THE WITNESS: No.

7 BY MR. LERNER:

8 Q. Okay. I mean, have you ever --

9 A. I don't do that as a, as a --

10 Q. Okay.

11 A. -- part of my job.

12 Q. Have you ever reviewed internal company
13 documents ever?

14 A. I would say that the, I've reviewed
15 several documents in this case. Primarily in the
16 Kessler report, there are excerpts of documents
17 from the --

18 Q. Okay.

19 A. -- internal corporate documents, but,
20 otherwise, beyond that, no. It's only the
21 documents I've seen, the few documents I've seen in
22 this case.

23 Q. So outside of the Kessler report, you
24 have not ever reviewed internal company documents?

25 A. Except there was a, I guess a couple that

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1 I've seen as part of -- I think Dr. Garcia's
2 deposition, there's some in there; yeah.

3 Q. Okay. Outside, I guess, of the IVC
4 filter litigation and outside of Dr. Kessler's
5 report and reviewing Dr. Garcia's deposition and
6 the exhibits, you have not previously ever reviewed
7 internal, internal company documents?

8 A. No.

9 Q. And you are not an FDA expert?

10 A. No.

11 Q. And you're not holding yourself out as an
12 expert as, into FDA compliance?

13 A. No.

14 Q. You also have not worked in any company
15 in post-market surveillance --

16 A. No.

17 Q. -- for -- okay. So you're not holding
18 yourself out as an expert in post-marketing
19 surveillance?

20 MR. O'CONNOR: Form and foundation.

21 THE WITNESS: No.

22 BY MR. LERNER:

23 Q. Do you have any experience developing
24 warnings for IVC filters?

25 A. Warnings?

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1 Q. Warnings.

2 A. No.

3 Q. No. And you're not offering -- strike
4 that.

5 You're not claiming to be an expert as to
6 warnings for medical devices or IVC filters?

7 MR. O'CONNOR: Object to the form of the
8 question.

9 THE WITNESS: No.

10 BY MR. LERNER:

11 Q. Have you ever had your expert opinion
12 excluded by any court, to your knowledge?

13 A. No.

14 Q. And you've never -- in all of the cases
15 we've talked about, you've never attempted to offer
16 an expert opinion in anything other than
17 medical-related opinions; is that fair?

18 A. That's true.

19 Q. All right. Now, I'm going to start
20 focusing more on the medicine now.

21 A. Okay.

22 Q. Are you still doing okay with time?

23 A. Oh, yeah. Yeah. I'm fine.

24 Q. Okay. Can you describe what the
25 difference between a DVT is and a pulmonary

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1 you recommend placement of IVC filters?

2 A. A dozen times, maybe.

3 Q. Okay. And has -- that dozen times, has
4 that changed at all, at all over the years, or has
5 that remained relatively consistent?

6 A. Pretty consistent. I mean, I think it
7 falls in that situation where you have someone that
8 has a blood clot you can't treat, and they're at
9 risk for pulmonary embolism.

10 Q. And so of all of the times -- I think I
11 already asked you this. So the times that you
12 recommended placement of a IVC filter have all been
13 within the parameters that are set forth in your
14 report?

15 A. Yeah, where you can't, you have an acute
16 DVT or a PE and you can't use an anticoagulant.

17 Q. Okay. And what is your role as far as
18 recommending, recommending a placement of an IVC
19 filter -- because you don't actually place the IVC
20 filter, right?

21 A. True.

22 Q. So do you recommend whether the filter be
23 a permanent filter or an optional filter, or is
24 that at the discretion of the interventional
25 radiologist?

1 A. Usually that's the interventional
2 radiologist because they -- we're -- it's --
3 usually when I'm in the situation where I recommend
4 a filter, it's we've been asked by critical care,
5 you know, someone in the critical care unit that
6 has a blood clot, and they're, they're asking us
7 how to treat this. And we say, No. You -- we
8 don't think it's safe to use an anticoagulant in
9 this situation. You need to consult IR to place a
10 filter, and we don't -- you know, I defer to my
11 colleagues in IR what, you know, what filter they
12 use, what, you know, whether they use permanents
13 or, or, you know, an optional filter.

14 I think they're using many fewer
15 permanents now because that's been, I think, the
16 wave, you know, in the U.S. Has been that permanent
17 filters are used a lot less.

18 As we had in that paper you can see, we
19 started using fewer and fewer permanent filters,
20 more optional filters.

21 Q. So you'd defer then to interventional
22 radiology as far as the type of filter, whether
23 it's optional or permanent and also the brand of
24 filter? Are you part of that decision-making --

25 MR. O'CONNOR: Object to the form of the

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1 patients is, is, one, you look at, All right. Did
2 they get the right prophylaxis after the procedure?
3 When was it started? Did they get all of the doses
4 of that prophylaxis after the procedure? And was
5 it an appropriate duration?

6 In some of them, there -- if their
7 duration was only two weeks, I put people on as
8 long as three months of anti-, you know, if you
9 look at the, the event curves for DVT or PE after
10 hip and knee surgery, a lot of them occur in the
11 first couple of weeks, but the event curve keeps
12 going upward after like three months and even a
13 little bit beyond that, so I've stretched people's
14 prophylaxis longer than that.

15 If I -- if I've done all of those things
16 by the third time, maybe, but I've never -- I've
17 never been in that situation where I thought a
18 filter would be the, you know, the right way to go.

19 I've always found some strategy whereby
20 we didn't have to put a, a filter in somebody;
21 yeah.

22 BY MR. LERNER:

23 Q. In the next paragraph of your report you
24 say, Thus, in order for physicians to make
25 reasonable risk-benefit assessments regarding

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1 filters, it is critically important that
2 manufacturers of IVC filters continuously apprise
3 the clinicians who order and implant IVC filters
4 about their safety profile, performance
5 characteristics, design problems and internal risk
6 assessments. What is the basis for that statement?

7 A. That comes -- I would say that we -- by
8 the time we got to this point in this document, we
9 had seen the Kessler report, and we added that,
10 added that in there.

11 So I think that's, that came, it come
12 from I guess both David and I's reviewing of the
13 Kessler report. We thought that maybe that had not
14 occurred in this case, and so we think that
15 that -- you know, if there were events that were or
16 testing had shown that there were problems with the
17 device that, that, that it maybe wasn't released in
18 a time, a timely fashion, so I think that's what
19 David and I are getting to.

20 Theirs, if you know there's a problem
21 with a drug or a device, as soon as you do know
22 that it looks like there's a problem there, you
23 ought to let the broader clinician world know about
24 it, and that's -- so that's not from literature.
25 That's from Dr. Kessler's report --

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1 Q. Okay.

2 A. -- on those documents.

3 Q. So that's --

4 A. And then we went on further to make
5 an -- it was, you know, we ought to make an
6 addendum on, that goes into, more in detail about
7 that report, or at least several points from it.

8 Q. Okay. So the statement here that in
9 order for physicians to make reasonable
10 risk-benefit assessments regarding, regarding the
11 filters, it is critically important that
12 manufacturers of IVC filters continuously apprise
13 the clin-, clinicians who order implant IVC filters
14 about their safety profile, performance
15 characteristics, design problems, internal risk
16 assessments, that was a personal opinion that, that
17 you and then Dr. Garcia had after reading the
18 Dr. Kessler report?

19 A. That is exactly --

20 MR. O'CONNOR: Object to the form.

21 THE WITNESS: Sorry. That's, that's
22 right. That's something we -- that's not something
23 coming from the literature. That's coming from
24 after seeing that report large -- yes.

25 BY MR. LERNER:

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1 Q. And, and you are not basing that
2 statement on any kind of FDA regulation standard or
3 some law. That's just kind of a personal opinion?

4 A. Yeah, that's after looking at those
5 documents.

6 MR. O'CONNOR: Object to the form of the
7 question.

8 THE WITNESS: Sorry.

9 BY MR. LERNER:

10 Q. And, and when you say that manufacturers
11 should continuously apprise physicians of certain
12 information, again, that's not based on any
13 particular regulation, standard or law. It's based
14 on your personal opinion?

15 MR. O'CONNOR: Form.

16 THE WITNESS: True.

17 BY MR. LERNER:

18 Q. And when you use the term continuously
19 apprise, are you saying that manufacturers should
20 be providing information to doctors how often?

21 A. I would say that if you have a -- you
22 know, obviously, I'm -- this is -- I'm an outsider.
23 The whole FDA, the vice pros, you know, approval
24 process or drug approval process, because I haven't
25 been involved with that either, but if you have --

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1 stuff that internal documents that he references in
2 that report, and we're -- they were -- they looked
3 at -- these showed large, you know, comparisons
4 between different filters, and Bard filters in
5 those. And I can't remember all of the different
6 comparators they, they have in those tables.

7 Q. Did you review any of the underlying
8 documents in Dr. Kessler's report?

9 A. I only reviewed the, the Kessler report
10 in itself, and he includes that data. And then
11 there's a couple of documents I guess -- although I
12 don't -- from Dave -- I mean, I think there are a
13 couple of exhibits in there that are communications
14 or something, interim communications that are --

15 Q. And for the, for the inter-device
16 comparisons that you're talking about, do you know
17 what the basis of the information is?

18 A. It -- from my recollection, they're
19 laboratory testing, testing, you know, different
20 animal models or bench-top models of like
21 resistance to like migration, for instance, and
22 pressure that's required for a device to migrate.

23 That's kind of what I recall from the
24 Kessler report, and then they have some analyses, I
25 think, of the MAUDE data by a, a statistician or

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1 something showing one filter is, like a Bard
2 filter, like a G2 is more prone to migration or
3 fracture than, than other filters. Again, this
4 is -- but that's all from the, the Kessler report.

5 Q. So you're not --

6 A. But I don't know the -- if you're asking
7 about what do I know, like all of the details of
8 how these tests are conducted, no. I'm looking at
9 the, you know, the snapshots of data that are in
10 the report.

11 Q. Right. And you're not an engineer?

12 A. No.

13 Q. You don't do testing of metal devices?

14 A. No.

15 Q. You've never created a bench test
16 yourself?

17 A. No.

18 Q. You may not even be able to interpret the
19 meaning of a bench test?

20 MR. O'CONNOR: Form.

21 THE WITNESS: No. I mean, I think
22 it's -- you can -- as anyone -- you know, anyone
23 can look at data can -- if there are differences
24 between devices, you can see one is different than
25 another, but you're right, I don't, I don't know

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1 Q. Right.

2 A. -- based on that.

3 Q. So it, it would be inappropriate and
4 unfair for you to review information that is
5 one-sided, wouldn't you agree?

6 MR. O'CONNOR: Form. Foundation.

7 THE WITNESS: Yeah. I mean, I guess if
8 there's -- we -- if we only saw part of the data,
9 then I think that would, yeah.

10 BY MR. LERNER:

11 Q. Sure.

12 A. Yeah.

13 Q. And you've spent about, I guess, almost
14 five hours --

15 A. Right.

16 Q. -- reviewing Dr. Kessler's report?

17 A. Right. Going through that, yeah.

18 Q. And he has a report and an addendum to
19 the report?

20 A. Yeah.

21 Q. Okay. So did you review both of those?
22 Like he has like a table that's connected with the
23 report?

24 A. I can't be -- I would have to go back and
25 look on my, my laptop and see if it's -- yeah, it's

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1 Q. Well, I'm just saying that whenever,
2 whenever you consider an issue, you want to
3 consider both sides of the story. It's not fair to
4 consider just one side of the story, right?

5 A. True.

6 MR. O'CONNOR: Objection. Form.

7 THE WITNESS: Of course, as a general
8 rule, yes. Yeah. Yeah.

9 BY MR. LERNER:

10 Q. Right. Have you ever spoken to
11 Dr. Kessler?

12 A. Never.

13 Q. Have you ever attempted to -- well,
14 strike that.

15 Have you attempted to be as accurate as
16 possible in describing Dr. Kessler's findings in
17 your report?

18 A. Yeah. We read through the report and
19 kind of pulled these right out, right out of his,
20 out of his report.

21 Q. So you didn't modify any of his findings
22 in what you --

23 A. I don't think so.

24 Q. Let me just finish my question.

25 A. Oh, yes. Sure. Sorry.

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1 Q. So in -- so you copied and pasted some
2 portions basically from his report into your
3 report?

4 A. There may not be directly copied and
5 pasted, but, you know, took data that he had his
6 report, in his report and put it in our addendum,
7 yes.

8 Q. Okay. But you didn't modify
9 Dr. Kessler's findings in any, any way?

10 A. I don't think so, no.

11 Q. You didn't change any of his findings in
12 the process of taking what you saw from his report
13 and inserting it into your report?

14 A. I don't -- I don't think so. No, I don't
15 recall doing that.

16 Q. So you included seven numbered paragraphs
17 in your report, your addendum repeating what
18 Dr. Kessler himself said in his own report?

19 A. Right.

20 Q. You, you don't add anything new about
21 Dr. Kessler's findings that Dr. Kessler himself
22 doesn't say in his own report?

23 MR. O'CONNOR: Form.

24 THE WITNESS: I don't think so, no.

25 BY MR. LERNER:

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1 Q. So, in other words, you're repeating in
2 your report some of the findings that Dr. Kessler
3 has found without changing anything?

4 A. Right. I think it's a summary of what we
5 read in the, in his, his report.

6 Q. But Dr. Kessler's findings do not factor
7 into your, the, the main opinions you're offering
8 in this, in this case?

9 A. Sorry.

10 Q. Sorry. Dr. Kessler's opinions do not
11 factor into the medical opinions that you're
12 offering in this case?

13 MR. O'CONNOR: Form.

14 THE WITNESS: Well, I mean, I think that
15 when we saw those, I think that was, certainly that
16 was -- I think the data he had in his report I
17 think were, we found were troubling and would make
18 one consider whether there were events that had
19 already occurred in, you know, in papers.

20 Like the Nicholson papers, for instance,
21 where they had a lot of fractures, this kind of
22 would support what they were saying. The Nicholson
23 paper only focused on G2 and recovery filters and
24 frac-, you know, frac-, you know, filter-like
25 fractures and stuff like that, but as these data

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1 He tells you basically that he went
2 through these internal documents and then produced
3 a report based on data that he has from internal
4 documentation, but I -- he doesn't have a method
5 section in his, in his, his report.

6 Q. So did you independently verify
7 Dr. Kessler's methodology?

8 MR. O'CONNOR: Form.

9 THE WITNESS: No.

10 BY MR. LERNER:

11 Q. Did you review any of the documents that
12 Dr. Kessler cites in his report?

13 A. No. Only the -- only the ones that are
14 in the report can I see, you know, where they have
15 data.

16 Q. When you say only the ones in his report,
17 you're saying you actually reviewed the report
18 and --

19 A. They're --

20 Q. -- descriptions in the report --

21 A. Yeah.

22 Q. -- about underlying documents? You never
23 actually pulled underlying documents?

24 A. True.

25 Q. Okay. Did you independently assess the

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1 reliability of the underlying data that Dr. Kessler
2 relied on?

3 A. I couldn't do that.

4 MR. O'CONNOR: Form.

5 BY MR. LERNER:

6 Q. Okay. Did you check or test any of the
7 assumptions that Dr. Kessler made about the data he
8 analyzed?

9 MR. O'CONNOR: Form.

10 THE WITNESS: Again, you could not do
11 that. Yeah.

12 BY MR. LERNER:

13 Q. Okay. Did you verify the documents that
14 Dr. Kessler reviewed actually showed what he says
15 they showed?

16 A. I --

17 MR. O'CONNOR: Form.

18 THE WITNESS: Again, I, I saw, read the
19 report. I don't have the, the documents it was
20 based on.

21 BY MR. LERNER:

22 Q. So you assume for the purposes of your
23 addendum that Dr. Kessler employed a reliable
24 methodology?

25 A. True. I mean, he's a -- he's got a very